K061922

# 510(k) Summary


* Applicant's Name ; Sentech Korea Corp.

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* Contact ; Mr. Soo Hyun, Kim / Managing Director


OCT 3 0 2006

1. Identification of the Device ;
Proprietary-Trade Name : AL-5000 Breath Alcohol Tester
Classification Name : Device, breath trapping, alcohol, DJZ
Common/ Usual Name : Breath-alcohol test system

2. Equivalence legally marketed devices :
AL-5000 is functionally similar to the AlcoMate CA2000.
KHN Solution LLC, K041334.

3. Indications for Use ( intended use ) ;
AL-5000 is intended to measure alcohol in the human breath.
Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

4. Description of the Device ;
AL-5000 is a Breath-alcohol tester designed to measure alcohol in the human breath. And AL-5000 is a D.O.T. approved device and a blow time of 3 seconds is required to capture an accurate deep lung sample.
AL-5000 is operated by gas sensor of semi-conductors type for the detection of blood alcohol concentration ( BAC ) from human breath.

The sensor consists of mainly sensing layer and heating element which is formed by a n-type semiconductor powder and heater, respectively.
In clean air, during the heater is powered, the oxygen molecules in the air traps the electron in the semiconducting material and then chemisorped on the surface of the powder particles. However, when it is exposed to organic vapor such as alcohol, the chemisoped oxygen ( O- or O2- ) is reacted with organic vapor and reduced.
By this reaction, the electrons trapped by oxygen is released and flow in the semiconductor. That is, when is exposed to organic vapor, the electrical conductivity increase ( the resistance decreases ).

5. Substantial Equivalence Chart ;

| Feature | AlcoMate CA2000 | AL-5000 |
|---|---|---|
| Indication of use | The device is intended to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication. | Same |
| Mode | Breath Alcohol Concentration | Same |
| Practitioner use | Over the counter | Same |
| Display | 3 Digit LED | Same |
| Power source | 9 Volt Alkaline Battery or auto cigar lighter (optional) | 2AA size Battery |
| Test automation | Single button operation | Same |
| Battery life | 300 tests | Over 200 tests |
| Measure range | 0.00-0.40% BAC | Same |

| | | |
|---|---|---|
| Type of sensor | Semi-conductive Alcohol Sensor | Same |
| Anatomical site | Mouth | Same |
| Mouthpiece | Washable | Disposable |
| Warm up time | Below 20 seconds | Below 21 seconds |
| DOT approval | Yes | Yes |
| Construction | Plastic case with internal circuit borad | Same |
| Size | 120x60x25 mm | 116x59x27 mm |
| Weight | 200 grams | 105 grams |

6. Conclusion :

Through a electrical safety, EMC and DOT tests, we, Sentech Korea Corp., came to the conclusion that AL-5000 is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Sentech Korea Corporation
c/o Laura Danielson
TUV America, Inc.
1775 Old Highway 8
New Brighton, MN 55412-1891

OCT 3 0 2006

Re: k061922
Trade/Device Name: AL-5000
Regulation Number: 21 CFR 862.3050
Regulation Name: Breath-alcohol test system
Regulatory Class: Class I
Product Code: DJZ
Dated: October 5, 2006
Received: October 12, 2006

Dear Ms. Danielson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K061922

Device Name: AL - 5000

Indications For Use : The Alco-Scan AL-5000 Breath Alcohol Tester is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

Prescription Use _____ AND/OR Over-The-Counter Use V
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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